UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

KM

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/051,843	06/29/98	WILLSON T	11373

HM12/0508

SCULLY SCOTT MURPHY & PRESSER
400 GARDEN CITY PLAZA
GARDEN CITY NY 11530

EXAMINER	
BASI, N	
ART UNIT	**PAPER NUMBER**
1646	19

DATE MAILED: 05/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/051,843	Applicant(s) Wilson et al
	Examiner Nirmal. S. Basi	Art Unit 1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 8, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 2, and 7-35* is/are pending in the application.

4a) Of the above, claim(s) *11-24, 26, 27, and 31-35* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 2, 7-10, 25, and 28-30* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1, 2, and 7-35* are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☒ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. Amendments filed 2/8/00 (paper number 17), and 10/16/00 (paper number 15) have been entered.

Response to Amendment

2. Acknowledgment is made of applicant's claim for foreign priority based on application filed in Australia on 10/23/95, 12/22/95 and 9/996 numbered PN-6135, PN-7276 and PO-2208 respectively. It is noted, however, that "Applicant respectively submit that certified copies of the foregoing applications will be filed in due course".

3. The drawings remain objected to because each Figure must described separately in the Brief Description of the Drawings. For example: a) Figure 1 should be labeled as Figure 1A, 1B, 1C, 1D, 1E and 1F and described in the Brief Description of the Drawings as Figure 1A-1F , or the equivalent, as required by 37 C.F.R. § 1.84 (u)(1). Similarly, Figures 3, 4, 5, 7 should be labeled and described accordingly. The rejection of the Brief Description of the Drawings is maintained, but, Acknowledgment is made of applicant's response indicating, "Applicant will Amend the BRIEF DESCRIPTION OF THE DRAWINGS, as well as the figure number in accordance with 37 C.F.R. § 1.84 (u)(1)m upon the indication of allowable subject matter". Applicant has added "BRIEF DESCRIPTION OF THE FIGURES", in paper number 15. "BRIEF DESCRIPTION OF THE FIGURES" should be amended to "BRIEF DESCRIPTION OF THE DRAWINGS"

Appropriate correction is required.

Claim Objection

4. Claim 30 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend on any other multiple dependent claim directly or indirectly. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits. Claim 30 indirectly depends on multiple dependent claim 10.

Further, Applicant elected Group II (1/10/00), pertaining to nuleic acid of SEQ ID NO:3 encoding the receptor of SEQ ID NO:4. The claims will only be examined as pertaining to nuleic acid of SEQ ID NO:3 encoding the receptor of SEQ ID NO:4. Reference to nuleic acid of SEQ ID NO:1 encoding the receptor of SEQ ID NO:2, which forms the basis of Group I (see office Action dated 10/4/99) must be removed from the claims.

Claim Rejection, 35 U.S.C. 112, second paragraph

5. Claims 1-2, 7-10, 25 and 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1- 2, 7-9 and 28-29 remain indefinite because it not clear what is a "derivative of said receptor". "Derivative" has not been defined in the claims nor specification so as to allow the metes and bounds of the claim to be determined. Applicant has directed the Examiners attention to Example 12 to provide adequate support for derivatives of the claimed nucleic acids. Example 12 does not provide a clear definition of derivative. Applicants arguments have been fully considered but not found persuasive for the following reasons: the claim remains indefinite because the term "derivative"

carries no weight in terms of structure and function and encompasses numerous alterations and reads on unrelated nucleic acid molecules, therefore the metes and bounds of the claim cannot be determined.

Claim 29 is indefinite because it is not clear what comprises an amino acid sequence derived from IL-4 receptor alpha-chain so as to allow the metes and bounds to be determined. The term derived from carries no weight in terms of structure and function and encompasses numerous alterations and reads on unrelated nucleic acid molecules, therefore the metes and bounds of the claim cannot be determined.

Claim 28 and 29 are indefinite because it is not clear what is implied by "interacts" the metes and bounds of the claim cannot be determined. The term "interact means to be acted upon. Act means to do thing: deed, something done voluntarily or the process of doing: action. It is not clear what deed or action is being done by the "interacts". If the applicant is referring to "interacts" to imply "binding", then the claim should be amended accordingly, to remove ambiguity.

Claim 7 remains indefinite because "low stringency conditions" are not specified. The metes and bounds of the group of sequences that would meet the limitations of the claim depend upon the precise conditions under which hybridizations were performed including wash conditions. Since the hybridization and wash conditions dictate which DNA sequences remain specifically bound to a particular nucleic acid the metes and bounds of the claims cannot be determined without the disclosure of said conditions. Applicant has directed the Examiners attention to page 7, lines 23-25 which, Applicant asserts, provides precise conditions under which hybridization are performed.

Applicants arguments have been fully considered but not found persuasive for the following reasons: Page 7, lines 23-25 do not provide a clear definition of "low stringency conditions". The specification states "Reference herein to a low stringency at 42°C includes and encompasses from at least about 1%v/v to at least about 15% v/v formamide--------to at least about 2M salt for washing". It is not clear what else low stringency encompasses, what range is encompassed by "at least about". Further since the "low stringency conditions" use the term "include" , this implies the conditions can be changed dramatically, and since the scope of the claim is dependent on the specific hybridization conditions, the metes and bounds of the claim cannot be determined.

Claims 2, 7, 10 and 29, is indefinite because the term "capable of interacting", "capable of interaction", "capable of directing", "capable of hybridizing" suggest other necessary but unnamed conditions that are required for interacting, directing or hybridizing. The recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. The metes and bounds of the claim are not clearly set forth. It is suggested the terms "capable of" be omitted from the claim.

Claim 30 are rejected for depending upon an indefinite base (or intermediate) claim and fails to resolve the issues raised above.

35 U.S.C. § 112, first paragraph

6. Claims 1-2, 7-10, 25 and 28-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated DNA (SEQ ID NO: 3) encoding a hemopoietin polypeptide (IL-13) comprising SEQ ID :4, does not reasonably provide enablement for other DNA. The, specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

While the person of ordinary skill in the art would, in light of the specification be able to isolate DNA encoding a polypeptide encoding IL-13 (SEQ ID NO:3), wherein the polypeptide comprises an amino acid sequence of SEQ ID NO:4, the scope of the claims, which encompass other nucleic acids derivatives encoding polypeptides are not enabled by the disclosure. The disclosure does not teach how to make such fragments, or to use a commensurate number of the DNA fragments which did not share IL-4 or IL-13 binding functions. Due to the large quantity of experimentation necessary to identify the polypeptides of instant invention, the lack of direction/guidance presented in the specification regarding the identification, purification, isolation and characterization of said polypeptides, the unpredictability of the effects of mutation on the structure and function of proteins (since mutations of SEQ ID NO:3 and 4) are also encompassed by the claim), and the breadth of the claim which fail to recite structural limitations, undue experimentation would be required of the skilled artisan to make or use the claimed invention in its full scope. For example in claim 28, if the two characteristics chosen are the derivative of (iii) and the polypeptide of having a molecular weight of 50,000 to about 70,000 of (iv), it is unpredictable

what function the polypeptide would have, or if it even be functional. A similar scenario can be contemplated for claim 29 subsections (iii)-(vi) are chosen to define the protein produced by the method.

The hybridization conditions of claim 7 have not been specified and do not constitute a meaningful structural limitation. Due to the large quantity of experimentation necessary to identify the polypeptides with the structural and functional features of instant invention without any disclosure of the hybridization or wash conditions, the unpredictability of isolating proteins related to SEQ ID NO:s 4, undue experimentation would be required of the skilled artisan to make or use the claimed invention in its full scope.

The instant fact pattern (claim 7) closely resembles that in Ex parte Maizel, 27 USPQ2d 1662 (BPAI 1992). In Ex parte Maizel, the claimed invention was directed to compounds which were defined in terms of function rather than sequence (i.e., "biologically functional equivalents"). The only disclosed compound in both the instant case and in Ex parte Maizel was the full length, naturally occurring protein. The Board found that there was no reasonable correlation between the scope of exclusive right desired by Appellant and the scope of enablement set forth in the patent application. Even though Appellant in Ex parte Maizel urged that the biologically functional equivalents would consist of proteins having amino acid substitutions wherein the substituted amino acids have similar hydrophobicity and charge characteristics such that the substitutions are "conservative" and do not modify the basic functional equivalents of the protein, the Board found that the specification did not support such a definition, and that the claims encompassed an unduly broad number of compounds.

Such is the instant situation. Clearly, a single disclosed sequence does not support claims to any nucleic acid hybridizing to same, given the lack of guidance regarding what sequences would hybridize specifically to SEQ ID NO: 3, and not other, related sequences. Likewise (claims 10, 25 and 28-30), expression vectors, cells comprising the vector of claim 10 and process for producing protein using said vector are not enabled for these reasons given above.

Claims 1-2, 7-9 and 28-30 claim derivatives of SEQ ID NOS:3-4 or derivatives of polypeptides that interact with Il-13 or IL-14 . The claims read not only on naturally occurring but also on non-naturally occurring proteins. Although derivatives IL-13 can be made said derivatives carry no weight in terms of structure and function and encompasses numerous alterations and reads on unrelated nucleic acid molecules. Further the applicant has not disclosed which derivatives would be expected to retain activity or how to use a commensurate number of said variants that are inactive. Due to the large quantity of experimentation necessary to identify the mutant, variant and derivatives with the structural features of instant invention without disclosed functional features, the lack of direction/guidance presented in the specification regarding the identification, purification, isolation and characterization of said mutant, variant and derivatives, the unpredictability of the effects of mutation on the structure and function of proteins (since mutations are also encompassed by the claim), undue experimentation would be required of the skilled artisan to make or use the claimed invention in its full scope.

Further, claim 25 is rejected based on the failure of the specification to enable one of skill in the art to make and/or use the pharmaceutical composition encompassed by the claim. The

pharmaceutical composition comprising the derivatives or compounds infers a drug or medication with therapeutic activity. The specification does not reasonably enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claim without undue experimentation. Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands (8 USPQ2d 1400 (CA FC 1988)). The factors most relevant to this rejection are the scope of the claim, unpredictability in the art, the amount of experimentation required, and the amount of direction or guidance presented. The term "pharmaceutical" implies a treatment of a disease. It is unpredictable what diseases could be effectively treated using a "pharmaceutical composition" comprising the derivatives and compounds encompassed by the claim. Neither the specification nor the prior art provide sufficient guidance as to what specific diseases could be treated by administering a "pharmaceutical composition" comprising the composition of claims 25. Attempting to identify a disease treatable by such a "pharmaceutical composition" would constitute undue experimentation. Therefore one of skill in art would have to identify a disease treatable by said "pharmaceutical composition", determine effective compositions, determine effective doses to achieve the intended purpose, determine routes of effective administration, determine if the "pharmaceutical composition" can reach its target tissue without degradation and determine if it has a therapeutic effect, all of which would constitute undue experimentation Therefore, the unpredictability to achieve all the afore mentioned goals and the lack of guidance provided in the specification, the disclosure fails to enable

one of skill in the art how to make and/or use the "pharmaceutical composition" encompassed by the claims 25.

7. Claims 1-2, 7-8, 10, 25 and 28-30 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing.

The claims are drawn to isolated DNA molecules

a) comprising derivatives of SEQ ID NOS: 3-4

b) comprising a nucleic acid that hybridizes to nucleic acid of SEQ ID NO: 3

c) derivatives of SEQ ID NOs:3-4 or encoding proteins capable of interaction with IL-13, derivatives of IL-13, complex with IL-4 and IL-4 receptor alpha-chain.

The claims are also directed to pharmaceutical compositions of a)-c) above.

Claims are further directed to Methods of producing recombinant polypeptide wherein the polypeptide has two of the following characteristics:

I) comprises SEQ ID NO: 4

ii) is encoded by SEQ ID NO: 3

iii) interacts with IL-13 or its derivative

iv) has a molecular weight between 50,000 to 70,000 daltons (western blot analysis)

and Methods of producing recombinant polypeptide wherein the polypeptide has three of the following characteristics:

I) comprises SEQ ID NO: 4

ii) is encoded by SEQ ID NO: 3

iii) interacts with IL-13 or its derivative

iv) has a molecular weight between 50,000 to 70,000 daltons (western blot analysis)

v) comprises an amino acid sequence derived from IL-4 receptor alpha-chain

v) is capable of interaction with IL-13 which is competitively inhibited by IL-4 in cells which express an IL-4 receptor alpha-chain

The specification discloses an isolated cDNA having the sequence of SEQ ID NO: 1 and 3, which encodes a polypeptide having the sequence SEQ ID NO. 2 and 4. The claims, as written, however, encompass polynucleotides which vary substantially in length and also in nucleotide composition. The broadly claimed genus additionally, encompasses polynucleotides which may be completely unrelated to polynucleotide SEQ ID NO: 1 and 3. For example, in claim 2, a derivative of SEQ ID NO:1 or 3 which is capable of interaction with a derivative of IL-13.

The instant disclosure of SEQ ID NOs: 1 and 3 does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera including full-length proteins,

chimeric proteins, fusion proteins, allelic variants, and variants, derivatives . The derivatives or variants may have no known or disclosed function. For example, in claim 2, a derivative of SEQ ID NO:1 OR 3 which is capable of interaction with a derivative of IL-13 may be a protein completely unrelated to instant invention, structurally and functionally. The polypeptides, encoded by polynucleotides isolated by hybridization may be completely unrelated to the polypeptide of SEQ ID NO:2 or 4. Further, polypeptides, comprising fragments, may also, be completely unrelated to the polypeptide of SEQ ID NO:2 and 4. A description of a genus of polypeptides may be achieved by means of a recitation of a representative number of polypeptides, defined by amino acid sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of polypeptides. There is no description of the conserved regions which are critical to the structure and function of the genus claimed. For example, what region or domain of the polypeptide of SEQ ID NO:2 or 4 contain a definitive structural feature required for protein function? The specification proposes to discover other members of the genus by using screening assays and techniques involving probes, primers, hybridization. There is no description, however, of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. Furthermore, the

prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polynucleotides encompassed. No identifying characteristic or property of the instant polypeptides is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of specific polypeptide and nucleotide sequences and the inability to screen, is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe, enable and use the genus as broadly claimed. For the reasons forth above, it does not appear that the inventors were in possession of the claimed derivatives and variants of claims 1-2, 7-10, 25, 30 and the methods of claim 28-29, at the time of filing.

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi
Art Unit 1646
May 7, 2000

Yvonne Eyler
YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600